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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,984	03/31/2005	Emadeldin M. Hassan	B4700-597US	6260

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WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
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EXAMINER	
SHTERENGARTS, SAMANTHA L	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
10/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,984	HASSAN ET AL.	
	Examiner	Art Unit	
	Samantha L. Shterengarts	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *claims filed 12 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 24-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 24-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendments filed 12 July 2010 are acknowledged. All rejections not explicitly maintained herein are withdrawn.

2. Claims 20 and 24-40 are currently pending.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 20, 24-25 and 27-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259).

Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, including gelatin, an acid-insoluble polymer, including hydroxypropyl methylcellulose phthalate, and an alkaline aqueous solvent (ammonia solution) (pg. 5, lines 21-40; Examples). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell (pg. 5, lines 25-27). Given this disclosed weight percent of acid-insoluble polymer therefore, it can be concluded that the remaining polymer is present at ratio of 30:70 (42%).

Venkateswara et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 6,331,316) teaches raising the pH of the coating suspension provides a more stable composition for an acid labile drug in the core (column 4, lines 39-42).

Matthews et al. teaches it is well known for enteric soft capsule shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely

optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

4. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

5. Claims 20, 24-25 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259).

Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer, including gelatin, an acid-insoluble polymer, including hydroxypropyl methylcellulose phthalate, and an alkaline aqueous solvent such as ammonia solution (pg. 5, lines 21-40; Examples). Further, the addition of plasticizers, preservatives, colourants, opacifiers and flavours can be included in the gel mass (page 5, lines 29-31). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell. Given this disclosed weight percent of acid-insoluble polymer therefore, it can be concluded that the remaining polymer is present at ratio of 30:70 (42%).

Venkateswara et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 2001/0051188) teaches when using an acidic enteric coating polymer, the pH of said enteric coating polymer is raised by using a suitable alkalizing agent such as sodium hydroxide. The pH of the enteric coating polymer is raised to a point which is below the pH wherein the enteric integrity of the polymer could be lost. This partial acid neutralization provides a more stable composition for the acid labile drug in the core (paragraph [0027]).

Matthews et al. teaches enteric soft capsule shells having a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

6. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Venkateswara et al. (WO 01/24780) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

7. Claims 20, 24-25 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259).

Okijama et al. teaches a gel mass composition comprising a film-forming, water-soluble polymer (gelatin or hydroxypropyl methylcellulose), an acid-insoluble polymer (cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate), an alkaline aqueous solvent (dilute aqueous solution of ammonium hydroxide), and optionally a plasticizer (PEG), and optionally, a

coloring agent (col. 3, lines 54-64; col.4, lines 31-38). Okajima et al. illustrates in Example 2 the ratio of acid-insoluble polymer to film-forming polymer being 50:50.

Okijama et al. is silent on the final pH of the gel mass being less than or equal to about 9 pH units and the instantly claimed moisture content.

Ullah et al. (U.S. 2001/0051188) teaches when using an acidic enteric coating polymer, the pH of said enteric coating polymer is raised by using a suitable alkalizing agent such as sodium hydroxide. The pH of the enteric coating polymer is raised to a point which is below the pH wherein the enteric integrity of the polymer could be lost. This partial acid neutralization provides a more stable composition for the acid labile drug in the core (paragraph [0027]).

Matthews et al. teaches enteric soft capsule shells having a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). The capsules taught exhibit an improved mechanical strength and will not crack or undergo substantial deformation during standard large scale capsule manufacturing procedures (column 1, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus,

absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

8. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 2001/0051188) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

9. Claims 20, 24-25 and 27-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259).

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It would have been prima facie obvious to one of ordinary skill in the art to increase the pH of the enteric soft capsule taught by Venkateswara et al. One would have been motivated to do so because Ullah et al. teaches that an increased pH provides a more stable composition for acid labile drugs which may be present the core. Further, one would have been motivated to modify the moisture content to be between 8-10% in order to ensure the integrity of the enteric soft capsules given that enteric soft capsules are known to crack or undergo substantial deformation during manufacturing per Matthews et al.

With respect to claims, 20, 39 and 40, the percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Furthermore, with regard to claims 20 and 35, the modification of the optimal pH of the claimed enteric soft capsule would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) as applied to claims 20, 24-25 and 27-40 above, and further in view of Shank et al. (U.S. 4,500,453).

The combination of Okajima et al. (U.S. 4,138,013) in view of Ullah et al. (U.S. 6,331,316) and Matthews et al. (U.S. 4,816,259) is set forth *supra*. The combination is silent on the use of gelatin extracted from animal bones or skins which has 100 to about 250 blooms.

Shank et al. teaches it is well known in the art that gelatin is used from animal bones and further gelatin obtained from animals contain lower molecular weight fractions. Further, Shank teaches that

enteric capsules which are made with gelatin have about 100 to about 250 blooms (columns 1, lines 22-26 and lines 67 to bridging column 2, line 21).

It would have been prima facie obvious to one ordinary skill in the art to utilize 100-250 blooms because Shank et al. teaches that enteric capsules are known to contain 100-250 blooms when using gelatin from animal bones.

Response to Arguments

It should be noted that arguments that have previously been presented will not be addressed herein as not to burden the record.

11.

Applicant alleges that the invention provides for a direct method for manufacturing enteric soft capsules without the need for coating the capsule with an enteric composition. Further, applicant argues that the capsule does not require cross-linking to gain its enteric character. This is not found persuasive. Applicant is guided to the breadth of their independent claim. Specifically, claim 20 is drawn to a composition. Therefore, in contrast to Applicant's allegation, the claims are NOT drawn to a method of manufacturing enteric soft capsules without the need for coating the capsule with an enteric composition. *Applicant alleges that the Examiner assumes that every component of the dried shell other than the enteric polymer in the composition would be a film forming polymer such as gelatin.* Applicant is again guided to the teachings of Venkateswara et al which discloses a composition comprising two polymer components: (i) a film forming, water soluble polymer and (ii) an acid insoluble polymer. Further, it is taught that one polymer component (i.e. acid insoluble polymer) comprises 40% by weight of the composition. Given that the composition is drawn to polymer components and further given that one polymer type is present at an amount of 40 percent of the composition it is reasonable to conclude that the remaining polymer composition is the second polymer component (i.e. film forming, water soluble polymer). Arguendo the above, it should be noted that Applicant has not set forth on the record what other components they believe are present in the composition instead of the second polymer component.

Applicant argues that the raw values of Venkateswara demonstrates that no ratio of enteric polymer to gelatin exceeds 10:30 (whole number 0.333) compared to 30:70 (whole number to 0.43) and alleges that this difference in ratio range is "substantially lower" and out of the range than those quoted in Venkateswara. It should be noted that this argument has previously been addressed in the Non-final Rejection mailed on 3/16/2010. Confusingly, though Applicant alleges Venkateswara does not teach or suggest a ratio, Applicant seems to concede that Venkateswara in fact does teach a ratio that does not exceed a ratio of 10:30. As previously stated on the record, the percentage of specific components present in the composition is clearly

a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results form the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. With regard to Applicant's allegations that the ratio is critical under alkaline conditions, this is not found persuasive. Applicant has not guided the Examiner has to *how or why* the ratio is critical. A review of the disclosure does not distinguish from the prior art or provide support. If applicant intends to rely on unexpected or unforeseen results, attention is invited to MPEP 716. Absent clear, convincing side-by-side data demonstrating unobviousness vis-à-vis the prior art commensurate with the scope of protection sought, the claims are considered prima facie obvious. Finally, Applicant seems to allege that the ratio is "substantially lower" this is clearly not found persuasive. As conceded by Applicant, the whole number comparisons are 0.33 vs. 0.43. It is not clear how Applicant has concluded that there is a "substantial" difference between these ratios.

Applicant alleges that the claimed ratio of enteric polymer to film-forming polymer was the lowest level of enteric polymer to achieve acceptable results and that lower ratios produced "border quality" compositions and thus Applicant concludes that the ranges by Venkateswara would not produce acceptable stability. Applicant has guided the Examiner to page 15, lines 22-29 in support of this allegation. This is not persuasive. Firstly, it should be noted that the composition found in the disclosure is not commensurate with that claimed. It is not clear how Applicant extrapolates the conclusions made on page 15 from these different compositions of Venkateswara. Again, Applicant is asked to provide additional guidance.

Applicant alleges that (i) the success of the alleged combination is not predictable, even if optimization is undertaken and (ii) the adjustments related to acid-labile drugs by Ullah et al. cannot rightly be presented as motivation to combine such teaching with any asserted teachings of Venkateswara which does not address the issue or problem. This is not found persuasive. Applicant has not set forth any reasoning or explanation as to how the above conclusions have been reached. Applicant fails to advance any specific reasons or evidence, aside from Counsel's own allegation, in support of this position that no motivation exists in the present obviousness rejection. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP 2145, which states "The arguments of counsel cannot take the place of evidence in the record."

Applicant alleges that Matthews discusses an enteric coating for gelatin capsules and the Ullah publication is drawn to a high drug load spheronized beadlet containing an acid labile drug and an enteric coating for such beadlet while the instantly claimed invention is drawn to an enterically coated soft capsule. It should be noted that the preamble is drawn to "an enteric soft

capsule shell formed from a gel mass composition." Preamble language are generally expressions of purposes and intended results, and as such are non-limiting since language does not result in manipulative differences in steps of claims. In re Hirao, 190 USPQ 15, 16-17, (CCPA 1976) held that the preamble was non-limiting because it merely recited the purposes of the process, which was fully set forth in the body of the claim.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626